4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0564]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0642. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Dietary Supplement Labeling Requirements and Recommendations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act -- (OMB Control Number 0910-0642)–Extension

In 2006, the Dietary Supplement and Nonprescription Drug Consumer Protection Act (the DSNDCPA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting for dietary supplements and nonprescription drugs marketed without an approved application. The DSNDCPA also amended the FD&C Act to add section 403(y) (21 U.S.C. 343(y)), which requires the label of a dietary supplement marketed in the United States to include a domestic address or domestic telephone number through which the product's manufacturer, packer or distributor may receive a report of a serious adverse event associated with the dietary supplement.

In the Federal Register of September 1, 2009 (74 FR 45221), we announced the availability of a guidance document entitled, "Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act." The guidance document contains questions and answers related to the labeling requirements in section 403(y) of the FD&C Act and provides guidance to industry on the use of an explanatory statement before the domestic address or telephone number. The guidance document provides our interpretation of the labeling requirements for section 403(y) of the FD&C Act and our views on the information that should be included on the label. We believe that the guidance will enable persons to meet the criteria for labeling that are established in section 403(y) of the FD&C Act.

In the Federal Register of August 24, 2015 (80 FR 51278), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

Table 1. -- Estimated Annual Third-Party Disclosure Burden[1]

Activity	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Domestic address or phone number labeling requirement (21 U.S.C. 343(y))	1,700	3.27	5,560	0.2	1,112
FDA recommendation for label statement explaining purpose of domestic address or phone number	1,700	3.27	5,560	0.2	1,112
Total					2,224

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The labeling requirements of section 403(y) of the FD&C Act became effective on December 22, 2007, although we exercised enforcement discretion until September 30, 2010, to enable all firms to meet the labeling requirements for dietary supplements. At this time, therefore, we expect that all labels required to include the domestic address or telephone number issued in section 403(y) have been revised accordingly. Thus our current burden estimate for this information collection applies only to new product labels.

In row 1 of Table 1 we estimate the total annual hourly burden necessary to comply with the requirement under section 403(y) of the FD&C Act (21 U.S.C. 343(y)) to be 1,112 hours. Using historical A.C. Nielson Sales Scanner Data, we estimate the number of dietary supplement SKUs for which product sales are greater than zero to be 55,600. Assuming that the flow of new products is 10 percent per year, then each year approximately 5,560 new dietary supplement

products are projected to enter the market. Estimating that there are 1,700 dietary supplement manufacturers, re-packagers, re-labelers, and holders of dietary supplements subject to the information collection requirement (using the figure 1,460 as provided in our final rule of June 25, 2007 (72 FR 34752) on the Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements, and factoring for a two percent annual growth rate), we calculate an annual disclosure burden of 3.27 disclosures (labels) per firm. Last, we expect that firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed and therefore believe that less than 0.2 hours (12 minutes) per product label would be expended to fulfill this requirement.

In row 2 of Table 1 we estimate the total burden associated with the recommendation to include an explanatory statement on dietary supplement product labels letting consumers know the purpose of the domestic address or telephone number to be 1,112 hours. Based upon our knowledge of food and dietary supplement labeling, we estimate it would require less than 0.2 hours (12 minutes) per product label to include such a statement.

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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